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ABSTRACT

The focus of the work of the Commission on Academic Medical Centers and the Economy of New England is the financing competitors strength and future development of academic centers and biomedical companies in New England. Among the findings and recommendations of the Commission are the following: (1) the New England region will require several replacements for the maturing computer industry, and biomedical industries are a strong contender; federal belt-tightening trends now underway could weaken the critical mass of research that leads to new biomedical technology; and the commercialization of U.S. biomedical research is being pulled abroad to Japan and Western Europe. Among the recommendations are that: (1) greater foundation support should be provided for biomedical research projects; and (2) medical-related companies should provide graduate and post-doctoral training fellowships; (3) each New England state should create a biomedical development grant program; (4) the New England states should create their own small business innovation research program to fill the gaps in funding provided under the federal program; and (5) New England municipalities should adopt the model guidelines of regulations governing biotechnological research and manufacturing promulgated by NIH (National Institutes of Health). An appendix lists medical schools and their major affiliated teaching hospitals in New England. (SM)

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BIOMEDICAL RESEARCH AND TECHNOLOGY

A prognosis for international economic leadership

COMMISSION ON
ACADEMIC MEDICAL CENTERS
AND THE ECONOMY OF NEW ENGLAND

JUNE 1988

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NEW ENGLAND BOARD OF HIGHER EDUCATION

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■ The New England region will require several replacements for the maturing computer industry. Biomedical industries are a strong contender, capable of generating new jobs and creating a "multiplier" effect among support services and suppliers. Many medical-related firms are poised for growth because of a strong international market and dramatic advances in technology.

■ Providing the driving force for biomedical industries is the biomedical research carried out in New England academic medical institutions and universities.

■ The commercialization of U.S. biomedical research is being "pulled" abroad to Japan and Western Europe. The commission's concern is that New England will lose the long-term economic benefits (jobs, taxes, income) of biomedical/biotech manufacturing.

■ Federal belt-tightening trends now underway could weaken the critical mass of research that leads to new biomedical technology.

■ Steps must be taken to strengthen biomedical research in New England and to capture more of the economic benefits that accrue from the development and manufacturing of biomedical/biotech products.

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■ Academic medical institutions can increase their research budgets by securing more industry sponsorship of research projects; obtaining revenues derived from licensing faculty inventions; and investing in business enterprises spun off from faculty inventions.

■ Greater foundation support should be provided for biomedical research projects.

■ Medical-related companies should provide graduate and post-doctoral training fellowships.

■ All states in the region should provide tax incentives to companies and individuals who donate equipment to institutions for biomedical research.

Commission Recommendations

Capturing the economic benefits of biomedical/biotech manufacturing 26

■ Each New England state should create a biomedical development grant program.

■ The New England states should establish their own Small Business Innovation Research programs which would fill the gaps in funding provided under the federal program.

■ The New England Board of Higher Education should undertake a survey to determine supply and demand for trained personnel with the skills required by biomedical/biotech firms.

■ New England municipalities should adopt the model guidelines of regulations governing biotechnological research and manufacturing promulgated by NIH.

■ The New England Governors' Conference should create a task force to consider state incentives for the production and manufacturing of biomedical/biotech products.

■ The New England congressional delegation should support legislation to broaden and make permanent the federal R&D tax credit and to revise the tax code to make R&D Limited Partnerships a viable source of research support.

APPENDIX 34

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Invaluable assistance to the commission was provided by Diane Fulman, consultant to Bank of Boston, and JoAnn Moody, associate vice president and legal counsel at the New England Board of Higher Education, who ably prepared and edited several drafts of the report.

Preface

In the fall of 1985, the New England Board of Higher Education created the Commission on Academic Medical Centers and the Economy of New England. The commission has evolved into a group of 45 distinguished medical, research and business leaders from throughout the region. The focus of the commission's work has been the financing, competitive strength and future development of academic medical centers (medical schools and their teaching hospitals) and biomedical companies in New England.

We were asked by NEBHE to undertake our work at the very time when the region will have to seek new sources of jobs and income. The maturing computer and computer-peripheral companies as well as the defense-related industries are no longer likely to be a major source of job creation. To be sure, these industries are healthy, but their growth impetus will be far less robust in the years ahead. The commission concluded early in its deliberations that the emerging biomedical and biotech companies would be important replacement industries and would, moreover, bolster the region's—and nation's—long-term competitive strengths in international markets.

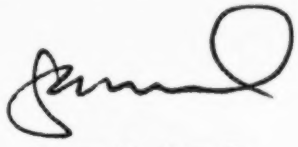
This commission report represents over two-and-one-half years of discussion and analysis. More than 40 meetings, seminars and site visits were held—bringing medical researchers, state legislators, venture capitalists and many others into our deliberations.

From these discussions we learned that New England's academic medical centers and biotech/biomedical firms—inextricably linked through basic and applied research and product development—are facing new and unprecedented challenges. Our academic medical centers are confronted with shifts in federal health-care funding and "belt-tightening" in biomedical research, while our biomedical firms must deal with increasingly aggressive international competition.

At the same time, commission members believe there is a strong basis for optimism. New England is without peer in the research and development base of its nine medical schools and their 46 major teaching hospitals, coupled with the R&D carried out by the region's established biomedical companies and younger biotech firms. The task ahead is to convert this research into a broad range of innovative products and services, generating expanded employment and income growth.

In the report that follows the commission members set forth five findings and 10 recommendations. We believe that these represent a realistic and practical approach for taking advantage of the unexploited opportunities at hand: identifying the means available for strengthening and commercializing biomedical research and mobilizing the resources of the region to realize our potential in this area. We fully recognize that these proposals will require new funding, but a careful review of our recommendations shows that the funds will come from within the region and largely through self-help collaborative efforts and entrepreneurial partnerships. Moreover, our recommendations are designed to achieve their maximum effectiveness in the dynamics of the market economy.

On behalf of all the commission members, we submit this report to the NEBHE board and our colleagues throughout New England. We hope that it will spark a region-wide dialogue, leading to new steps to strengthen our biomedical research and development base and capture the ensuing economic benefits for the region.



James M. Howell
Chairman
Commission on Academic Medical Centers and the Economy of New England

Foreword

In creating the Commission on Academic Medical Centers and the Economy of New England, the New England Board of Higher Education believed it was essential that a highly qualified and diverse group of leaders examine the future of biomedical research and its implications for the regional economy. The deliberations of the commission further extend the focus of NEBHE's work on the relationship of higher education to the dynamics of regional economic development. In appointing the commission in 1985, I requested their insight with respect to a three-point charge:

- To assess the collective scale and competitive strength of New England's nine academic health centers and associated teaching hospitals, with particular emphasis on R&D capacity
- To analyze New England's future biomedical leadership role within the context of anticipated change and the advent of emerging technologies, new processes and health-diagnostic systems
- To recommend steps to enhance the future economic contributions of academic science, with particular attention to the future of the medical centers and the emerging biomedical/biotechnical enterprises of the region.

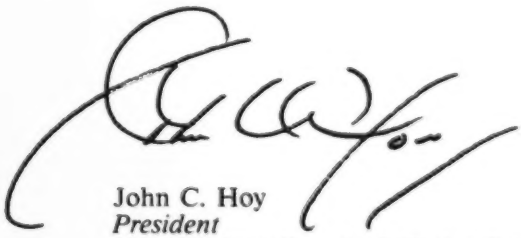
The concentration of biomedical research in New England is preeminent by national and international standards. However, there has been inadequate regional public policy attention directed to the exceptional impact and promise of biomedical research and development. The continued development of cutting-edge biotechnology enterprises in the region requires broad-based public understanding as well as strategic investment by state government.

The commission's report again reveals heightened evidence that quality education from elementary school through college in the fields of science and mathematics is the bedrock of the region's knowledge-intensive industries. Superb preparation and support are also essential for those students who would pursue graduate degrees in biochemistry, genetics, biophysics, bioengineering and the health professions.

New England's world-renowned medical schools, major teaching hospitals and universities collectively form what one member of the commission has called "a unique national treasure." Yet, biomedical development is internationally competitive, and the global impact of biomedical discoveries on behalf of all peoples increases daily. Higher education represents the seedbed of our biomedical industries, making it possible for New England to assume a world leadership role.

If successful biomedical technology transfer offers, as the commission persuasively argues, the promise of creating a major new replacement industry in New England, then the current level of public understanding is dangerously inadequate. Progressive planning and continued nurturing are essential. The commission wisely urges that New England vigorously pursue balanced investment in the future of biomedicine.

The New England Board of Higher Education is confident that the commission's findings will be reviewed with care, forming the basis for substantial regional discussion and action.



John C. Hoy
President
New England Board of Higher Education

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Overview of Biomedical Research and Development in New England

During the past decade, New England has become synonymous with economic growth and technological innovation—and, indeed, in recent years has been the envy of the world. Since 1975 the New England economy has generated more than 1.57 million new jobs; the region's unemployment rate, at 3 percent, remains well below the national average; and per-capita personal income is 17 percent above the national norm.

The region's success at technologically based growth can be attributed largely to the presence of several critical resources. Clearly, New England's 260 undergraduate colleges and research universities are such a resource and their importance to the region's economy has been well-documented. Without quality higher education the technology-driven transformation of the New England economy would not have occurred. However, far less has been written about another of the critical resources that has contributed to the region's technical development: the unique concentration of academic medical centers.*

In the fall of 1985, the New England Board of Higher Education created a commission to examine the role of academic medical centers in the region's economy. An earlier NEBHE commission had produced a report entitled *A Threat to Excellence,* released in 1982, which focused on the relationship of higher education to the New England economy. This report succeeded in raising awareness within the region of a negative trend in our region's capacity to educate, and in mobilizing broad support for new policies and actions to restore our region's competitive educational edge.

Members of the present NEBHE commission believe that its work can have an equally significant impact. In this connection, a major goal of the commission has been to assess—and to develop new ways to enhance—the economic impact of these medical centers. During the commission's deliberations, it became clear that while these centers were world-renowned for their excellence in patient care and medical education, and while their local economic role as major employers and purchasers of goods and services was recognized, their broader impact on the economy was not widely understood. This is especially the case for their central role as generators of pioneering research and medical advances that lead to new technologies and entirely new industries. In this respect, they are major contributors to discovery, innovation and, through technology transfer, new business opportunities and jobs. Review of this aspect of academic medical centers became the major focal point of the commission's work.

Academic medical centers also play a unique, but often underappreciated, role as urban institutions. As a major employer of minorities and inner-city residents, as a health-service provider to city dwellers who cannot afford treatment, and as an "anchored" institution in the community, the future of the city and the academic medical center appear to be inextricably linked. In undertaking its work, the commission recognizes that as one prospers, so will the other. Thus, initiatives that help to assure the continued vitality of academic medical institutions will invariably help to improve the economic condition of their cities.

During the course of the commission's deliberations, considerable time was devoted to a discussion and assessment of federal and state cost-control measures in health care and the impact of these measures on the operation of academic medical centers in New England. Commission members decided, however, that our final report should not focus on health-care cost control. Prominent in our thinking was the recognition of health-care cost control efforts underway at the national and state levels. Furthermore, extensive study and analysis of the system for financing medical education has been undertaken by the Commonwealth Fund and others.

Noting that biomedical research and job creation were especially promising areas because of their long-term impact on the economy and technological growth, commission members agreed that a compelling statement on the critical role of biomedical research was needed. Moreover, commission members concluded that an improved and broader understanding of biomedical research and development could ultimately provide the region with new insights into the complex and continuing debate surrounding health-care cost financing. This viewpoint is even stronger today than when the commission began its work.

* Academic medical centers are defined as medical schools and their major affiliated teaching hospitals. Nine medical schools are included in this report—Boston University Medical School, Harvard University Medical School, Tufts University Medical School, the University of Massachusetts at Worcester, Dartmouth Medical School, the University of Vermont Medical School, the University of Connecticut Medical School, Yale University Medical School and Brown University Medical School—as well as 46 major affiliated teaching hospitals. (See Appendix.) There are 435 major teaching hospitals and 127 medical schools in the United States.

FINDING: The New England region will require several replacements for the maturing computer and computer-peripheral industries. Biomedical industries are a strong contender, capable of generating new jobs and creating a "multiplier" effect among support services and suppliers. Many medical-related firms are poised for growth because of a strong international market and dramatic advances in technology.

The commission's efforts come at a watershed time for the New England economy. Looking ahead into the decade of the 1990s, it is becoming apparent that many of the existing high-tech industries, especially the manufacturing segment of the computer and electronic-components industries, are in a later phase of their development and, therefore, will no longer generate jobs at the rate the region has experienced for the past decade. Furthermore, technological advances for the computer and computer-related industries are not expected to have the same dramatic impact on employment as the introduction of the mini-computer or the micro-computer.

Federal defense spending, while still economically significant, has already leveled off and is expected to become a less important driving force in regional growth. While defense projects in New England, particularly in Massachusetts and Connecticut, generated a steady stream of new jobs between 1981 and 1986, defense spending is expected to slow in the late 1980s and then gradually decrease in the 1990s.

Given the outlook for the computer and defense-related industries, the current critical challenge for New England is seeking out the next technologically advanced replacement industries in which the region has a competitive edge.

Biomedical Industries: The "Next Wave" Technologies

Increasingly, the biomedical industries—broadly defined in this report to include the medical-related products of genetic and cell engineering (biotechnology)*, as well as traditional pharmaceuticals, medical instrumentation, devices and equipment—are being viewed as having special potential as sources of economic growth.

There are two major reasons why the biomedical industry holds such promise. First, the largest markets for medical products—the United States, Europe and Japan—will steadily expand as the proportion of aged citizens in these countries continues to enlarge dramatically. Citizens over 65 are the heaviest consumers of medical services and products. Second, the expectation is that innovations and advances in medical treatment and products will spur increased use by all population groups. These innovations will continue to drive the industry and help generate growth and new jobs.

The estimated volume of the U.S. biomedical industries is considerable—amounting to approximately $25 billion in 1980 alone.* Nationwide, it is the larger, well-established medical instrumentation as well as the chemically based pharmaceutical companies that account for the "lion's share" of this total. In New England, the medical instrumentation and supply sector represents a significant part—$2 billion—of the biomedical industry. Twenty percent of total U.S. sales of biomedical instruments (such as intensive care and fetal monitors, defibrillators, X-ray and surgical devices) are sold by New England manufacturers.

An important new segment of the biomedical industry is therapeutic and diagnostic agents created by biotech firms using genetic and cell manipulation. Examples are human growth hormone, human insulin, hepatitis-B vaccine and quick tests for strep throat and diabetes. The New England biotech industry consists of approximately 85 firms, 50 in the Boston area alone and others scattered throughout the region, which are typically younger and cover a broad range of new products and services.

Although some are engaged in research relating to agriculture or environmental clean-up, most of the biotech firms in the region are concentrated on projects that have medical/pharmaceutical applications.** Many of New England's biotech firms are newly-formed, small, innovative companies—whose yield in economic "dividends" for the region, though largely long-term, holds significant potential.

In fact, while biotechnology is only just beginning to be translated into jobs, income and production capacity, many of the companies that have moved into the production stage already

* Biotechnology includes any technique that uses living organisms or products derived from them to make or modify products.

* See Edward B. Roberts and Oscar Hauptman, "The Financing Threshold Effect of Success and Failure of Biomedical and Pharmaceutical Start-Ups," Working Paper 1681-1-86, Sloan School of Management, Massachusetts Institute of Technology, May 1986, p. 2.

** Indeed, as noted in the study, *Biotech 88: Into the Marketplace*, conducted by the Arthur Young High Technology Group, the large pharmaceutical industry may be transformed by the techniques of biological manipulation being perfected by small biotech companies.

have shown impressive job creation as they begin to "grow up." Indeed, five of New England's fastest-growing companies are biotech. Sales at Genetics Institute, for example, grew by more than 900 percent from 1982 to 1986, with the number of employees increasing more than fourfold to 288. Over the same period, Genzyme Corp. experienced an almost 400-percent increase in sales growth, with job expansion more than tripling.

These firms, like the more traditional biomedical companies, not only create jobs internally, but also spawn a variety of companies that provide support services, as well as other technology-based enterprises. It is this multiplier effect—extending benefits to companies in other industries and in other parts of New England—that has been the hallmark of the computer industry, and which promises to enhance the economic impact of the biotech and biomedical industries.

Why New England?

The biotech industry, in particular, has several characteristics that should be especially important to regional, as well as national, policymakers. First, the discoveries in DNA research and the techniques of recombinant DNA and monoclonal antibody production are new and fundamental—direct outgrowths of university or academic medical center research undertaken in the NIH-funded "war on cancer." New England academic medical institutions are especially active in recombinant DNA and monoclonal antibody technologies.

Second, the biotech industry flourishes in an environment that encourages risk-taking and innovation. New England fosters precisely the kind of opportunistic environment in which technological breakthroughs are likely to occur. At the same time, the existing biotech firms serve as role models for would-be biotech entrepreneurs who want to successfully pursue their own innovative ideas.

Third, the growth and financing of biotech firms in New England do not follow the same pattern as that of the computer industry. Far more capital—on the order of 100 times more—has been required to translate an idea into a biopharmaceutical product than, for example, is needed in the software industry.* Also, a far longer development time—four to seven years—is required,

* As software becomes more complex and costly to develop, this ratio may well be reduced.

Biotechnology... The Most Promising New Industry

The U.S. Congressional Office of Technology Assessment and other experts view biotechnology—the abilities to splice and recombine genes and to fuse and clone other cells—as not only the next major technological wave of the 20th century but also as capable of surpassing computer and microchip technology in economic importance. Applications are expected across many industrial sectors including pharmaceuticals, plant and animal agriculture, specialty chemicals and food additives, mining and oil recovery, environmental clean-up, commodity chemicals and energy production.

Biotechnology, moreover, is consistently cited as one of the most promising new industries in all six states by state legislative, business and educational leaders, in the "Future of New England" survey carried out in 1987 by the New England Board of Higher Education.

Biotech Companies are "Brewing Cures"

Biotech companies in Greater Boston, like those across the region, appear to be "brewing a cure" for everything from cancer and AIDS to the common cold. Consider the following examples:

- **Genetics Institute is developing a drug (tissue-type plasminogen activator, or TPA) shown to dissolve blood clots that cause heart attacks.**
- **Biogen recently received FDA approval for its alpha interferon, shown to be effective against a rare form of leukemia in human clinical trials, and is a leader in the development of gamma interferon, a promising treatment for rheumatoid arthritis and certain kinds of cancer.**
- **Biotechnica International will soon announce a DNA probe to detect gum disease.**
- **Genzyme is the leading independent supplier of the key active components—enzymes and substrates—used by manufacturers of clinical diagnostic kits for diabetes, and for coronary artery and pancreatic diseases.**
- **Damon Biotech, anticipating a huge market for anti-cancer uses of monoclonal antibodies, is shifting into large-scale synthetic manufacture of antibodies using fermentation vats and procedures.**

largely due to federal regulations requiring demonstration of safety and efficacy in clinical trials.* Federal research funding is not on the scale of computer and aerospace projects underwritten by the National Aeronautics and Space Administration and the Department of Defense; and while the federal government has been the major purchaser of computers for missile guidance and other defense purposes, it is not the dominant market for biotech products and services.

Fourth, biotechnology in New England, as well as biomedicine, is marked by a geographical concentration of outstanding academic medical centers and the presence of MIT, together constituting an unparalleled biomedical R&D infrastructure. At MIT alone, 35 percent of ongoing research is medical-related. Moreover, there are extensive research collaborations between MIT and medical faculty throughout the region. Also, MIT is closely affiliated with the Whitehead Institute of Biomedical Research. In 1986, MIT received an NSF grant of $20 million to establish the National Center for Biotechnology Process Engineering, underscoring its continuing role in biomedical research and its commercial application.

For these reasons, biomedical industries, including the fledgling biotech firms with their revolutionary advances, are a good match for the business climate of New England. In addition to their direct impact on job creation and income growth, their multiplier effect—by indirectly creating new markets for supplies and services and spinning off new technologically based firms—could be sizable.

FINDING: Providing the driving force for biomedical industries is the biomedical research carried out in New England academic medical institutions and universities.

The region's medical schools and major teaching hospitals conduct a substantial portion of the nation's biomedical research. The nine schools and 21 of the 46 teaching hospitals in New England have substantial research budgets, each of which exceeds $1 million annually. Funds awarded by the National Institutes of Health, the principal source of funding for medical research, give some indication of the importance of this research (see following table). With 5.3 percent of the total U.S. population, the New England region in 1986 captured 15.6 percent of the total NIH research grant dollars, 14.2 percent of NIH fellowships and training grant dollars, and almost 55 percent of total NIH research and development grant dollars to independent hospitals (which include university-affiliated but not university-owned voluntary hospitals). The Boston area captures more biomedical research funding from NIH than any other metropolitan area in the United States.*

NIH total grants and awards: 1986

NEW ENGLAND STATES (in thousands of dollars)	
CONNECTICUT	$121,763
MASSACHUSETTS	473,137
RHODE ISLAND	21,352
MAINE	9,495
NEW HAMPSHIRE	16,219
VERMONT	18,935
NEW ENGLAND	**$ 660,901**
UNITED STATES	**$ 4,440,434**

SOURCE: NEBHE analysis (January 1988) of data from NIH Data Book, 1987.

But, federal dollars for direct research tell only part of the story. Significant research findings arise from the fact that academic medical centers are not merely engaged in research, but are also actively involved in patient care and medical education. Indeed, it is the research prompted by clinical problems, presented by patients, that often leads to the development of medical inventions or biomedical agents.**

A commission member, Dr. J. Robert Buchanan, General Director of Massachusetts General Hospital, explained the difference at a round-table discussion held at NEBHE headquarters:

"The first step in developing a good biomedical research project at an academic medical center is to be able to ask the right questions, to have the right problem to work on. More often than not,

* It should be noted that the FDA has been accelerating the approval process by which it evaluates new drugs for their safety and efficacy.

* But note that inflation and other factors have cut the purchasing power of these grants. See page 16.

**New England academic medical centers have pioneered a wide range of medical advances, including chemotherapy and hyperthermia in treating cancer, the use of the laser as a scalpel in surgery, stimulating the growth of new blood vessels and artificial skin for burn and trauma victims, and treating hypertension with drugs.

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what identifies the right problem is a patient presenting medical staff with something intriguing, different and challenging. The patient starts a series of questions being asked. Ultimately, these questions translate into research programs and hopefully, in time, often through some very circuitous and labyrinthian route, the loop is closed back—perhaps not to the same patient, but to similar patients who benefit from an advance in medical treatment."

Because the clinical research performed at academic medical centers almost always involves human subjects or was prompted by patient care problems, it is likely to have the potential for commercialization and for significant benefit to the public. Business investors understandably find it easier to assess the market demand and manufacturing feasibility of products possibly arising from this applied biomedical research than from basic laboratory ("bench") research.

Traditionally, academic medical centers have drawn on their own research budgets for some of these patient-oriented, early-stage research projects. Academic medical centers also perform an invaluable service by undertaking later-stage clinical testing of medical equipment and drugs. This later-stage clinical investigation—including the period of clinical trials, the testing of new procedures and the refinement of new technologies—is the most expensive period of product development. Although clinical trials are typically sponsored by a federal grant or a private company, the academic medical center often does not capture the full costs through overhead on these grants and has typically used some of its own internal funds.

Because of the public and commercial significance of both patient-oriented biomedical research and late-stage clinical trials undertaken in academic medical centers, extensive ties have developed between researchers at these centers and biotechnological, pharmaceutical, medical device and instrumentation corporations. At the New England Medical Center, a Boston teaching hospital, 30-40 percent of the faculty are engaged in consulting, creating new products and companies, or supervising researchers in companies—and this day-to-day involvement in technology transfer is typical of many of the region's academic medical centers.

The process by which corporate leaders formally and informally consult with researchers at academic medical centers and at MIT, monitor their publications and exchange views with researchers as well as venture capitalists about the public uses and marketplace demands for a new invention or process, also serves as a major con-

Biomedical research dominates New England's biotech industry

It is not surprising that New England's fledgling biotechnology industry is largely biomedical in nature, given the critical mass of biomedical research performed in the region. With the collaboration and advice of medical and university researchers, these and other medical-related firms are involved in commercially developing an array of devices, instruments, and microorganisms that will transform human health care, from prevention of disease and disorders to diagnosis to treatment to cure.

For example, Ventrex Labs in Portland, Maine is now selling a five-minute diagnostic test (based on monoclonal antibodies) to detect strep throat; a tiny firm in West Haven, Conn., MicroGeneSys, has produced an AIDS vaccine which was approved for human clinical tests by the U.S. Food and Drug Administration on Aug. 18, 1987; newly formed Medarex, a joint venture of Dartmouth Medical School and the New Jersey firm, Essex Chemical Co., is locating in Hanover, N.H. and plans to commercialize certain monoclonal antibodies to bind to harmful cells; West Greenwich, R.I. is welcoming a new biopharmaceutical firm, WelGen Manufacturing, Inc. (a joint venture of the Boston-based Genetics Institute and the England-based Burroughs Wellcome Corp.); Biotek Instruments in Winooski, Vt., founded in 1968 by a medical professor at the University of Vermont, makes equipment that tests, calibrates and measures medical products and also produces spectrophotometers purchased by research scientists.

duit for technology transfer in the medical field. For example, recent advances in monoclonal antibodies have stirred intense medical and commercial interest in their possible diagnostic and therapeutic uses.

Given the unique regional density of first-rate research activities in New England's academic medical centers, it is not surprising that these connections between the business sector and the medical researchers are growing. Moreover, the financial community and the public at large are becoming more familiar with the medical and economic potential of laboratory inventions in improving the diagnosis, treatment and prevention of disease. It has been the central role of this commission not only to enhance this understanding, but also to devise an agenda that would facilitate the growth of these medical-related industries in New England.

FINDING: The commercialization of U.S. biomedical research is being "pulled" abroad to Japan and Western Europe. The commission's concern is that New England will lose the long-term economic benefits (jobs, taxes, income) of biomedical/biotech manufacturing.

Despite New England's extraordinary strength in biomedical research and the presence of established as well as young biomedical and biotech companies bringing medical innovations to the world marketplace, there is growing concern that New England and the United States may not retain dominance in the market.

One aspect of this concern is that Western Europe and particularly Japan will seize New England medical discoveries arising from basic research, quickly commercialize them and "sell them back to us." The development of the videocassette recorder has followed that pattern. Japan now holds nearly 100 percent of the market for this invention originally created by U.S. and British engineers.

There are, indeed, disturbing signs that New England and the United States may not retain dominance in the market for biomedical products. One sign is the aggressiveness of large pharmaceutical houses in Europe and Japan, which are often ahead of their counterparts in the United States in seizing opportunities through partnerships and licensing agreements to gain the right to manufacture and/or market promising new U.S. products.

This development has led a commission member, Michael Hooker, president of the University of Maryland, (Baltimore County Campus) and chairman of the Commercial Bi-

Biotechnology in an Environment of International Competition

It is clear that at present the United States and Japan dominate. "U.S. efforts to commercialize biotechnology are currently the strongest in the world," primarily because of the unparalleled excellence here in basic life-science research, the aggressive entrepreneurial spirit and willingness to take risks and the availability of venture capital (Congressional Office of Technology Assessment).

But Japan may not be in second place for very long. The Japanese have high regard for the economic potential of biotechnology; many of their large firms, as well as the Ministry for International Trade and Industry, have been devoting substantial resources to the industrial scale-up and commercialization of various biotech products. Several European countries and their major pharmaceutical houses, for their part, are offering financial, manufacturing and employee training assistance as well as marketing partnerships to the myriad of small new biotechnology firms in the United States (approximately 300). By these overtures, the European nations hope to capture a part of American biotechnology as it enters its production and manufacturing phase.

otechnology Advisory Panel to the U.S. Congressional Office of Technology Assessment, to conclude that in order to raise capital for clinical testing and to obtain marketing and distribution assistance, some biotech companies must "give away the store."* A very large problem looming on the horizon, adds Hooker, is that so many foreign companies have now bought sizably into U.S. biotech firms that they will be able to influence many corporate practices in the future, such as the siting of manufacturing facilities. Commercialization is also "pulled" abroad because Japan and Western Europe have created conditions—including less regulation and fewer legal restrictions, as well as long-term capital financing, tax incentives and employee training programs—favorable to the commercialization of early-stage research initiated in the United States. In short, the young U.S. and New England biotech industry must evolve in an environment that has already been internationalized and is highly competitive.

The commission has become increasingly concerned over this development. Referring to the loss of biotech production and manufacturing facilities overseas, commission member Mark Skaletsky, chairman of Enzytech and former President of Biogen, asked, "New England is the acknowledged leader in biotech. We're getting the front end of it; how can we retain the back end of it?"

Thus, the commission's concern is based on the economic consequences for the region; namely, that New England may not be able to capture the long-term economic benefits (jobs and taxes) of biotech manufacturing. Our concern is also that abundant capital from abroad directed at New England research will eventually succeed in moving research discoveries, and perhaps top-flight researchers themselves, from New England to Western Europe and Japan. If the region can create a more hospitable environment for commercializing biomedical R&D, it will capture more economic benefits, and also be able to nurture other research enterprises here.

FINDING: Federal belt-tightening trends now underway could weaken the critical mass of research that leads to new biomedical technology.

Yet, at the very time that this international competitive challenge has emerged in the biomedical field, strong and understandable national and state efforts to control health care costs are likely to make the role of academic medical centers in pioneering biomedical research less secure. Moreover, with the increased concern about the slower growth and instability of the national economy during the 1988-90 period, additional program cuts undoubtedly will be forthcoming.

In terms of constant dollars, federal government funding for patient-based biomedical research, including NIH grants, is now being systematically reduced. In 1986 total NIH funding in current dollars had increased by approximately 4.2 percent over 1985; however, its value had substantially decreased. A Biomedical Research and Development Price Index developed by the Commerce Department's Bureau of Economic Analysis suggests that a dollar awarded by NIH in FY 1986 was the equivalent of slightly more than half (52 cents) of the buying power of a FY 1977 dollar.

Further, Professor Federico Welsch of the Harvard-MIT Division of Health Sciences and Technology, in recent testimony before the NIH Director's Advisory Committee, points out that the cost of carrying out scientific research has increased not only because of inflation but also because of the increasing complexity of the questions asked and the intricate technology and equipment needed to answer these questions. Welsch suggests that, on average, a realistic deflator (to bring 1986 figures in line with 1977 figures) would be approximately 66 percent higher than the deflator used in the Biomedical Research and Development Price Index. The shrinking of the constant federal research dollar that is taking place has led New England academic medical centers to table some of their research projects and more are likely to be curtailed.

But the damage does not end with the reductions in direct research funding. The training of new researchers—the region's research "seed corn"—is at risk. As a result of the federal government's shift to fiscal restraint, a wide range of biomedical training programs are being cut back as well. NIH now commits only 4.9 percent of its total budget to training; in 1971, it committed 11.5 percent.

Research funding also will be dramatically affected by changes in patient-care reimbursement under the federal Medicare program (a portion of which covers research projects and graduate medical education, or clinical residencies, at teaching hospitals). In the fiscal year 1988 budget, reimbursement for Medicare patients will be based on a single national rate, with the amount of reimbursement depending on the patient's discharge diagnosis. Because of regional differences in the cost of medical care, this will discriminate against

*At the time Hooker became a member of this commission he was president of Bennington College in Vermont.

institutions in those parts of the country where quality is high and costs reflect advanced methods of patient care, such as New England, the Middle-Atlantic States and California.

At the same time, the prospective payment system for Medicare patients originally provided an 11.6 percent add-on to compensate academic medical centers for the extraordinary operating costs associated with their urban locations, the severity of illnesses they confront and other unique costs of research medicine. This adjustor has now been reduced to 8.1 percent, with a resulting loss to centers that will run into millions of dollars annually. Moreover, the Federal Office of Management and Budget plans to further reduce the adjustor to 4.05 percent.* The consequences of these cuts have yet to be felt, but they will become severe in the next five years. And, at the same time that academic medical center administrators prepare for these cuts, they are also being called on by local officials to modernize their equipment and provide more care for indigent patients.

Unless new funding sources are developed, the critical mass of biomedical research being performed in New England will most likely be weakened by these federal budget cuts. As a result, the creative loop from research back to improved patient care will be drastically weakened. And, over time, the marketplace spin-offs from outstanding world-class biomedical research will diminish in New England. Thus, while the commission members support national fiscal restraint, we also recognize that the impact of the cuts in the health-care and biomedical fields will be most uneven—falling disproportionately hard on New England. Our central concern in this report is the long-term competitiveness of New England: the region must continue to be a major international player in medical-related industries.

* Health Policy and Research News, *The Blue Sheet*, 1/13/88, p. 8.

FINDING: Steps must be taken to strengthen biomedical research in New England and to capture more of the economic benefits that accrue from the development and manufacturing of biomedical/biotech products.

Members of the commission recognize that academic medical centers are a unique source of intellectual and scientific advantage for the region, and one of the critical resources for future growth in biomedical activity. Moreover, we have concluded that the time has come for policymakers to take action that will prevent the adverse impact on research of the "belt-tightening" trends now underway. Similarly, attention must be devoted to finding new ways to enhance the potential for the commercialization of research that has been taking place in New England. Our view—as reflected in the recommendations contained in this report—is that small but critically targeted shifts in public and private policy can help to preserve the stream of biomedical technology that has flowed to the region from the interaction between New England's academic medical centers and the private sector.

Commission Recommendations

Commission Recommendations: Strengthening Biomedical Research in New England

In the following section the commission outlines four recommendations for strengthening biomedical research in New England. There are other research concerns that are not fully addressed by these recommendations, because acceptable remedies seem to be underway.

For example, biomedical research facilities are outmoded throughout the United States but especially in the urban centers of New England. At the request of U.S. Sen. Lowell Weicker, R-Conn., member of the Senate Committee on Labor and Human Services, NIH in 1988 will report to Congress on the effects of the discontinuance in 1969 of NIH's Extramural Facilities ("bricks-and-mortar") program. This program provided grants that were responsible for the construction of many of New England's existing biomedical research facilities. Sen. Weicker is also requesting NIH to investigate the feasibility of a pilot program that would provide funds for the construction of new and/or expanded biomedical research facilities. In addition, the Boston Redevelopment Authority and other agencies in New England are taking steps to assist several medical schools and teaching hospitals with their acute needs to expand and upgrade their research buildings.

A major goal of the commission is to stimulate public discussion of the following recommended solutions, with the hope that they, too, will receive effective and long-overdue attention. At the same time, one should bear in mind that the funding sources for many of the recommended actions are not exclusively federal and state government. Rather, the commission strongly believes that, while government funds are sought in some of the recommendations, additional revenues must also come from more entrepreneurial management of the academic medical centers themselves and through expanded and new partnerships with industry, foundations and state government.

■ **ISSUE: Insufficient funding for biomedical research at academic medical centers.**

Declines in federal research funding and cuts in federal reimbursements for teaching hospitals that impact on research were discussed at length earlier in this report. As was noted previously, the value of NIH biomedical research funding has substantially decreased over the past decade when the effects of inflation, as well as the costs of addressing increasingly complex research questions, are taken into account. Thus, as cited earlier in this report, the buying power of a dollar awarded by NIH in FY 1986 was equivalent to slightly more than half (52 cents) the buying power of a FY 1977 research dollar. Clearly, the trend poses a serious threat to the competitiveness of the biomedical research enterprise, especially in New England.

It is unlikely that this trend can be easily reversed. A creative response is needed by academic medical centers, leading to new sources of revenue for research.

■ **RECOMMENDATION: Academic medical institutions can increase their research budgets by securing more industry sponsorship of research projects; obtaining revenues derived from licensing faculty inventions; and investing in business enterprises spun off from faculty inventions.**

Academic medical centers in New England report success in incrementally increasing industry support of research projects undertaken by their faculty. On average, about 10-15 percent of these institutions' research funding now flows from industry. New England Deaconess Hospital is a noteworthy exception: 30 percent of its $7 million research budget is derived from industry support, up from zero in 1982.

The commission believes that academic medical centers should take steps to increase and broaden their interaction with the business sector, with the goal of attaining additional industry underwriting for their research.*

First, academic medical centers should more effectively publicize the biomedical research underway in their institutions. For example, directories of research are now available from Dartmouth College and Medical School and the

* Commission members further believe that these steps can be taken by the centers, while at the same time maintaining academic freedom and opportunities to openly disseminate research findings.

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Hoechst sponsorship of MGH research

A long-term relationship between giants is illustrated by the $70-million, 10-year research agreement between the West German pharmaceutical company, Hoechst, and Massachusetts General Hospital, entered into in 1981. The research funding has underwritten an entirely new department of molecular biology at MGH; in return, the company may choose to exercise exclusive licenses of any biotechnological inventions arising from the sponsored research. In addition, at any one time the company can send up to four employees to work and be trained in the new department and over the 10-year life of the contract can send up to 40 employees, provided the hospital deems their qualifications acceptable.

University of Connecticut Health Center. These should be replicated on a broader regional basis, ultimately through the design and implementation of a computerized system linking in-house medical researchers and industry research directors.

Second, a lecture or seminar series would bring business leaders to the academic medical center to discuss the research underway. Yale University's Office of Cooperative Research, established in 1982, sponsors an ongoing lecture series designed to accelerate the dialogue among academic researchers and business officials.

The University of Vermont, in the process of building a closer relationship between its medical and agricultural schools, is exploring ways to inform the business community inside and outside Vermont of its innovative work in molecular biology.

The commission believes that such initiatives will spur more sponsored research by U.S. corporations. As an example, Integrated Genetics, Inc. of Framingham, Mass. has established a formal program for keeping abreast of biotech research: three full-time company scientists devote themselves solely to finding and helping to fund projects that fit into the long-term product plans of the corporation. The scientists' job, according to a company spokesman, consists of keeping up with the latest academic journals, meeting with university liaison people and going to scientific seminars and meetings.

Obtain revenues derived from licensing faculty inventions

While some revenues are now being derived from the patenting and licensing of faculty inventions, there is considerable evidence that many exceptional ideas are not being commercially exploited to the maximum extent. A noteworthy study of two major MIT laboratories reveals that while 49 percent of laboratory scientists and engineers in the survey claimed to have made discoveries that had commercial applications, a surprising two-thirds of this group did not attempt to do anything with their ideas.* These findings are remarkable given the institutional expectation that MIT faculty will seek to apply their ideas to the solutions of real-life problems.

The finding that many exceptional ideas are not translated into commercial and public uses is reinforced by NEBHE interviews, undertaken as a part of this commission's deliberations, with

* Edward B. Roberts, "Influences on Innovation: Extrapolations to Biomedical Technology," *Biomedical Innovation*, edited by E.B. Roberts et al, MIT Press, 1981, p. 53.

medical researchers throughout New England and consultations with directors of university technology licensing offices.

Academic medical centers can address this issue by securing in-house staff to provide the liaison with faculty members and the business community—ideally, through technically-trained and business-oriented professionals who can fully grasp the significance of faculty researchers' work and aggressively explore commercial possibilities. The in-house liaison officer at New England Deaconess Hospital in Boston, for example, attends medical seminars, keeps current with his faculty's work, and has built a productive working relationship with researchers and the outside business community based on his own medical and business background. The University of Connecticut Research and Development Corp. is actively developing several medical inventions with the help of a diverse board of directors, and recently cofounded a venture capital club in Hartford in order to improve the financial climate there for technology transfer.

A caveat, however, is in order. In-house staff should be carefully chosen for their technical expertise and especially their entrepreneurial attitudes. At a meeting with commission members, Edwin C. Whitehead, founder and benefactor of the Whitehead Institute of Biomedical Research at MIT, characterized in-house technology transfer efforts at the present time as "generally ineffective" and concluded that it is "almost a disgrace that so much royalty income has escaped the research institutions over the years."*

Too often in-house staff, the commission has found, are excessively occupied with the legal aspects of technology licensing. At another meeting with several commission members, Neils Reimers, head of Stanford University's Technology Licensing Office, noted that most in-house officers underplay support and encouragement to faculty as well as competent and aggressive marketing of faculty inventions to large and small businesses that will bring the inventions to the marketplace. In 1986 Reimers was brought in to completely reorganize and restaff the MIT Technology Licensing Office. The office's legal orientation was replaced with a technical and marketing orientation; the new MIT office now licenses as many faculty inventions in two months as the former did in a year.

Regardless of the alternative used to improve technology transfer—in-house liaison officers, shared-cost arrangements with other institutions, and/or contracting with outside technology-transfer corporations to provide some or all of the needed services—royalty and licensing can be significant. A number of research universities have established formulas for allocating royalty income—such as 25 percent to the inventor, 25 percent to his/her department and 50 percent to the institution. The equity of allocation formulas should be periodically examined. The key point is that systematically exploring the commercial possibilities of research and marketing the inventions can yield new sources of revenue for teaching hospitals, medical schools and research universities.

Invest in business enterprises

Investing in start-up companies is already occurring on a limited basis. Dartmouth Medical School in the summer of 1987 announced that it is forming a joint venture company with Essex Chemical Corp. to market monoclonal antibodies developed by faculty researchers. Possessing equity in the company and the opportunity for license income, Dartmouth anticipates entering into similar transactions in the future. Brown University, through its Research Foundation, also intends to involve itself as an equity holder in companies and products generated by its faculty. By investing $25 million, Boston University in October 1987 acquired a majority stake in Seragen, a biotech firm capitalizing on a hybrid molecule technology invented by Boston University medical researchers.

In addition to investing in spin-off companies, the commission believes that academic medical centers should examine new ways to invest their own operating funds in the clinical testing of devices and drugs taking place in their facilities. In return for this financial assistance, or in-kind contributions, the institution would receive a portion of the royalties flowing from the marketed product.

Admittedly, in-kind or capital investments in spin-off enterprises by academic and medical institutions can move forward only after it can be established that there is no conflict of interest and that the institution's mission will not be compromised.

■ **ISSUE: Insufficient financial support to researchers engaged in basic research on independent projects.**

As mentioned earlier, in terms of constant dollars, federal funding for biomedical research has dramatically decreased. A study by the Massachusetts Committee for the 1987 NIH Centen-

*Whitehead is also a venture capitalist and heads Whitehead Associates in Greenwich, Conn. He is founder and former chairman of Technicon Corp.

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nial has shown that, in 1976, a young researcher after finishing his/her training had almost one chance in two of receiving a positive response on a research application presented to NIH. Today, a similar researcher has only a one-in-three chance. Given that NIH provides 90 percent of all biomedical research funding in the United States, this is a disappointing ratio.

Furthermore, the number of individuals 35 years of age or younger applying to NIH for research grants has declined precipitously. According to data from the *Peer Review Notes* of the NIH Division of Research Grants, in 1979 that age group accounted for 26.1 percent of the total applicants requesting grants. By 1986, the figure had dropped to 13.4 percent. The slim chance for independent funding, according to medical administrators on the commission, is discouraging gifted individuals from entering biomedical research and forcing researchers early in their careers to abandon the field. Moreover, the shortage of available funds is increasingly becoming a problem for more established researchers.

■ **RECOMMENDATION: Greater foundation support should be provided to biomedical researchers pursuing independent projects.**

At a time when the number of federal basic research grants is declining, a greater number of foundations should underwrite scientific or medical research projects. Presently, only 5 percent of total giving by foundations is directed toward such research. While recognizing that a number of foundations are constrained by the mandates imposed by their founders, the commission would also point out that foundations have considerable freedom to direct their activities which, in at least some cases, could be used to flexibly support new directions in biomedical research. This can be accomplished through grants, especially to younger biomedical researchers who for the first time are seeking an independent source of funding for a research project.

Whatever the means of encouragement, the financial resources must be in place to make this a reality. Accordingly, the commission recommends that NEBHE conduct in-depth meetings with key regional and national foundations to review their priorities with respect to biomedical research and development.

■ **ISSUE: Inadequate financial support for training graduate and post-doctoral biomedical researchers.**

Graduate students and post-doctoral fellows are finding it acutely difficult to secure financial underwriting for their research training. In 1986, the NIH budget committed only 4.9 percent to the training of biomedical scientists; 17 years ago, in 1971, it was 11.5 percent. This decline is even more disturbing given the widely accepted view that: "We have the cheapest and best source of our scientific productivity in our graduate students and post-doctoral fellows."* Commission members are understandably concerned about the diminishing support for the next generation of biomedical researchers.

■ **RECOMMENDATION: Medical-related companies should provide post-doctoral training fellowships.**

Established medical instrumentation, supply and pharmaceutical companies as well as the newer biotech firms in New England should assume responsibility for helping to train the next generations of biomedical researchers in New England.**

The Massachusetts Biotech Council should encourage its member companies to fund a program along the lines of the Massachusetts High Technology Council model. Under guidelines created by MHTC in 1980, its member companies are asked to provide 2 percent of their research budgets in support of higher education in the Commonwealth.

In 1986 alone an estimated $70 million from MHTC member companies was spent in pursuit of this so-called "2-Percent Solution." A significant portion of this money has been spent on fellowships for master's degrees or Ph.Ds. Some of the funds are earmarked to encourage Ph.Ds to teach rather than to enter the private sector; other funds are used to establish a direct relationship between a fellowship recipient and a specific company.

Even a modest effort along these lines undertaken by biomedical and biotech companies would be an important first step and, once underway, could be supplemented with other sources of fellowship funds.

* Dr. Paul Berg, Nobel Laureate and professor of biochemistry, Stanford University.

** The commission notes with concern the diminishing competency of American students in math and science. Commission members believe that unless this weakness is addressed, our students will not have the basic skills that are a prerequisite for research careers.

Underwriting for fellowships should be sought not only from medical-related businesses and charitable foundations but also from wealthy individuals. The University of Texas Medical Center in Dallas recently announced that it will receive $20 million over 10 years from businessman H. Ross Perot. The funds will be used to enable five students to undertake seven years of graduate work culminating in a joint M.D.-Ph.D. degree, to fund two post-doctoral research training positions and to sponsor research projects on cholesterol reduction by two Nobel Laureates at the medical center. Other contributors are being sought, with the hope of fully underwriting 15 entering M.D.-Ph.D. students each year.

■ **ISSUE: Outmoded research equipment.**

Any major increase in NIH funding for sophisticated research equipment—such as lasers, spectroscopy, nuclear magnetic resonance and X-ray crystallography—is doubtful in the near future.* By contrast, Japan and West Germany, according to the Massachusetts Committee for the 1987 NIH Centennial, provide generous government support for biomedical equipment. Unquestionably, this will remain a matter of concern given the highly technical and sophisticated nature of the research. But the issue of support for equipment at the lower end of technology research has surfaced as a problem as well.

Funding for less sophisticated and expensive equipment is also important—and obtaining such support may be more politically feasible. The director of research administration at Brown University Medical School points out that her institution needs replacement and purchase of several pieces of computer-related equipment ranging in cost from $5,000 to $15,000. Physician-researchers at Deaconess Hospital in Boston have noted that similarly modest sums would make the difference in maintaining several important research projects.

■ **RECOMMENDATION: States in the region should provide tax incentives to companies and individuals who donate equipment to institutions for biomedical research.**

The New England states should enact tax incentives that provide a direct credit for contributions of state-of-the-art biomedical equipment to qualifying organizations. Of the states in the region, only Rhode Island has established such an incentive, offering a tax credit of 8 percent of the excess over $10,000 of cash or property contributed for use in a scientific research program conducted by an institution of higher education. Louisiana permits a credit reaching up to 40 percent of a taxpayer's state tax liability for contributions of research and technological equipment to a qualifying educational institution. California allows for an additional deduction for research property donated to universities and other institutions of higher education.

Utilizing credit instead of deduction provisions is a far more powerful (albeit more costly to the state) incentive since the credit directly reduces the applicable tax whereas the deduction only reduces the tax burden by the amount of the effective tax rate. Further, in Massachusetts, individuals cannot deduct charitable contributions, so a credit provides the only available source for a tax benefit.

Finally, given the clustering of biomedical/biotech firms around teaching hospitals, medical schools and universities, there may be feasible ways for the firms and academic institutions to cost-share and time-share new research equipment and, in the process, further nurture academic and industrial collaboration.

* The cost of X-ray crystallography equipment, for example, ranges from $250,000 to $300,000.

Commission Recommendations: Capturing the Economic Benefits from Biomedical/Biotech Manufacturing

One of the principal focal points of this commission is concern over the strength of the New England economy. We know that academic medical centers are important to the region's economy. We know, moreover, that they are viable sources of technology transfer, leading to new business enterprises. What we have attempted to accomplish in this report is to build on the recognized value of academic medical centers, look for new means of strengthening their research function, and find ways in which the regional economy can benefit—in terms of jobs and income—from the new enterprises that emerge from their complex activities.

Unquestionably, the states can and should play a major role in this process. In this connection, it is worth noting Japan's efforts to provide a "comfortable home" for biomedical/biotech companies. Japan is coordinating trade, pricing and health-care policies to promote pharmaceutical innovation and expand biotechnology. While it would be unrealistic to pattern the role of New England states closely after the Japanese model, our recommendations indicate that new state initiatives could make a difference.

In this section of the report, the commission has focused on an area that is especially responsive to changes in state policy: the removal of barriers to biomedical job creation. To this end, six recommendations are proposed, which, taken together, would enable New England to capture more of the economic benefits that accrue from the development and manufacturing of biomedical/biotech products. The implementation of these recommendations does not rest solely with new funding, but with the creation of new collaborative processes as well.

Although several recommendations focus on the medical aspects of biotechnology, it is important to bear in mind that they have considerable relevance for biotechnology's future in the chemical, energy, agricultural and pollution-control industries as well. The steps recommended in this section will also be helpful in securing a more hospitable environment in the region for these industries.

■ **ISSUE: New approaches are needed to encourage collaboration in applied research between technology-based companies and academic medical centers.**

The U.S. Congressional Office of Technology Assessment as well as the U.S. Department of Commerce have recently published comprehensive analyses of America's strengths and weaknesses in the commercialization of biotechnology. Not surprisingly, European and Japanese competitors seem to have the edge in the commercialization of biotechnology because of their long-standing experience in applied research. Japan will likely continue to rapidly exploit the results of basic research available from other countries, especially the United States. And, with other Pacific Basin countries moving up the technology ladder, international competition in this industry can only become more intense.

One of the ways to strengthen applied research in the United States generally, and New England specifically, is to foster greater collaborative efforts between the biomedical business sector and academic medical centers. The two recommendations that follow are directed toward this end.

It is noteworthy in this connection that the New England states as a region provide a smaller percentage of funds than states in any other region in the underwriting of both basic and applied research. According to NEBHE analysis of National Science Foundation data, only 2.3 percent of 1986 R&D expenditures at doctorate-granting institutions in New England is derived from the six state governments, comparing unfavorably to a national average of 8.4 percent.

These aggregate regional ratios, however, may be somewhat misleading and thus require additional comment. Shown in the following table are the state-by-state data.

State R&D Expenditures at Doctorate-Granting Institutions: 1986

	Total State Dollars	State Award Per Capita
Connecticut	$ 4,351,000	$ 1.36
Maine	796,000	.68
Massachusetts	11,286,000	1.94
New Hampshire	3,188,000	3.10
Rhode Island	939,000	.96
Vermont	1,929,000	3.57
New England	**$ 22,489,000**	**$ 1.77**
California	23,921,000	.88
Louisiana	32,251,000	7.17
Maryland	36,095,000	8.09
Texas	85,124,000	5.10
United States	**$883,209,000**	**$ 3.67**

Source: NEBHE analysis (4/88) of data from: *Academic Science/Engineering:* R&D Funds, FY 1986, 1987; and U.S. Dept. of Commerce Bureau of Census, *State Government Finances in 1986* (GF86-No.3) October 1987.

It is difficult to read a pattern into these ratios, especially when one considers state-by-state variances in the public-private university mix and the clustering of the academic medical centers. Nonetheless, there are two distinct New England patterns: a strong R&D spending commitment by Vermont and New Hampshire and a low spending commitment in the other four states in the region. In sharp contrast to all the New England states are the high ratios for state R&D support in Louisiana, Maryland, and Texas. The low spending ratio in California reflects, to some extent, the high level of federal support in research and development grants.

The commission members strongly believe that the New England states must improve on their past performance in R&D spending because their longer-term competitiveness in the biomedical industries is on the line. We have shown earlier in this report that when adjusted for inflation and other factors, federal research dollars are declining and consequently state funds must be used to augment federal research support. Also, federal research grants carry restrictions and in many cases cannot be targeted to more applied research. Finally, as a region we are spending far less than our counterparts in other areas of the country with smaller agglomerations of science and technology.

Nonetheless, an increased spending commitment is not enough. As the following recommendation indicates, there must be an appropriate and responsible mechanism to channel the funds to the biomedical research and development firms if economic benefits are to be maximized.

■ **RECOMMENDATION: The commission recommends that each New England state create a biomedical development grant program.**

While there are modestly funded matching-grant programs in several New England states that seek to encourage collaboration between technology-based firms and universities, the commission proposes the creation of a state-supported Biomedical Development Grant Program to promote applied biomedical research. Where programs with similar goals are already in place (see sidebar), the commission recommends that they be strengthened with respect to funding, administration and operation. Enactment of this grant program in the New England states would enable New England companies engaged in applied research with a significant impact on biotech/biomedicine to have access to, and a timely response from, the best research facilities in the region. These companies would thereby be better able to maintain and increase their competitiveness in the international market.

The proposed biomedical development program would operate along the following lines: any company in the region developing medical-related products, equipment, processes or services that could benefit from participation in collaborative research with an academic medical or research institution could apply for grant funds. To receive funds, the company must demonstrate a joint partnership on a specific research project to be conducted with a research/medical institution. The program would be available only to New England-based business firms, and the grants could only be used in partnership with established, non-profit research facilities, medical schools, teaching hospitals and universities. Thus, the program would "write down" the cost of applied research within the operational efficiencies of the market economy.

Decisions on the allocation of funds would be made by a committee consisting of scientific advisors drawn from the academic medical community and advisors from the finance community (especially venture capitalists). Because the proposed Development Grant Program would be limited to New England-based companies and New England-based research facilities, it would provide a direct impetus to internalizing the economic benefits of the emerging biomedical/biotech industry within New England.

The proposed program would have additional goals to those of the programs already in

place: enhance the R&D capabilities of fledgling biotech and biomedical firms as well as established instrumentation and equipment companies; "marry" the capabilities of these firms with academic medical centers, in particular; and, through reciprocity legislation with the other New England states, induce firms to engage in these research projects with institutions throughout the region.

Where no comparable program has been enacted, the commission recommends the adoption of legislation to implement the "model" biomedical development grant program.

■ **RECOMMENDATION: The New England states should establish their own small-business innovation research programs which would fill the gaps in funding provided under the federal program.**

The commission recommends that each of the New England states establish a state Small Business Innovation Research program, providing matching grants to in-state companies that receive Phase I grants under the federal program. The federal program—created in 1982 and currently funded at $400 million annually—requires federal agencies that spend $100 million or more a year for outside research to set aside 1.25 percent for small-business innovation. These contracts, awarded on a competitive basis, are designed to stimulate the growth of small science- and technology-based companies.

Federal awards are divided into three phases. Phase I provides up to $50,000 for six months of feasibility-related research. Phase II, aimed at financing the development of prototype products, provides up to $500,000 for two years of related R&D for Phase I projects found to be most promising. In Phase III, private-sector capital sources, with perhaps some government financing, are used to commercialize the new technologies. A small company can use up to one third of its Phase I and one half of its Phase II grants for academic collaboration, including help from academic medical centers.

Milton D. Stewart, president of the Small Business High Technology Institute—an organization working to improve the effectiveness of SBIR and extend its impacts—maintains that Phase I funding of $50,000 under the federal program is often insufficient to carry a company to the point where Phase II funding is received. As a result, several states now make small contributions to supplement Phase I funding, but only New York state provides a full match of Phase I funds. However, Rhode Island is initiating a program that will provide free proposal consulting services and several additional financial incentives

Collaborative research projects are underway

Massachusetts, Rhode Island and Connecticut now have in place matching grant programs that seek to nurture collaborative research projects between industry and academic research institutions. The Massachusetts Centers of Excellence Corp. distributes matching government grants to projects in several designated areas, including biotechnology. In addition, the new 75-acre Massachusetts Biotechnology Research Park in Worcester seeks to promote alliances between its commercial tenants and the academic and medical establishment in the geographical area. Rhode Island's new Partnership for Science and Technology also intends to spark collaboration among business and the academic/medical communities through financial assistance of joint applied-research projects.

Finally, Connecticut has begun a Cooperative High Technology Research and Development Grant Program (one of the targeted areas is biotechnology). The director of the program reports that the response from the business community in terms of proposals has far exceeded expectations.

to encourage qualified companies to participate in Phases I and II, and Connecticut has begun to make $15,000 bridge grants to assist firms as they await a decision on their Phase II applications.

What is noteworthy is that New England scores very high in the number of SBIR awards it receives (five of the six New England states are among the top 15). In other words, very promising applied-research proposals have emerged from New England companies; this research is more likely to produce commercializable results with additional funding through state SBIR programs.

State SBIR programs should be well worth the effort. A Price Waterhouse survey has found that firms participating in the federal SBIR program increased their employment by an average of 25 percent after they received their contracts, and that 44 percent of the contracts resulted in new high-technology products and services.

■ **ISSUE: There are an inadequate number of trained personnel with the skills required by biomedical/biotech firms for production and manufacturing.**

The Congressional Office of Technology Assessment and the U.S. Department of Commerce report, in particular, a shortage of bioprocess engineers (engineers with a background in chemistry and biology). These skilled personnel are necessary for the design and monitoring of biological "scale-up" processes for production and manufacturing, including large-scale fermentation vats and separation and purification machinery needed in obtaining large quantities of specialized micro-organisms for pharmaceutical and other industrial purposes. At most, only about 10 percent of the recent master's degrees and doctorates in chemical engineering in the United States are ready to assist with bioprocess scale-up without additional formal training in biology.

While Japan, West Germany and the United Kingdom have maintained a strong academic base for the bioprocess industries, the United States has not. Japan, in fact, has the largest supply of bioprocess engineers and industrial microbiologists, mostly because their specialty chemical and other industries have kept the demand high for graduates with this training.

■ **RECOMMENDATION: The New England Board of Higher Education should undertake a survey to determine supply and demand for trained personnel with the skills required by biomedical/biotech firms.**

The commission recommends that NEBHE undertake a comprehensive survey to determine specifically the extent to which existing graduate educational programs will be able to meet the demand for bioprocess engineers. As an integral part of this survey, we strongly recommend that programs providing training for other skills that are critical to the biomedical/biotech industries also be assessed. The survey—including larger biotech and biomedical firms as well as new start-ups and younger companies—should be updated on a regular basis to insure the timeliness of its findings.

Several New England universities are beginning to respond to the bioprocess specialist shortage, but their efforts may not be adequate.* For example, Worcester Polytechnic Institute's department of biology and biotechnology is working to prevent a critical shortage of trained people for jobs that didn't exist two years ago. A spokesman at WPI adds that "all predictions point to a rapid rise in the need for specialists in bioprocess engineering." The first of its kind in the country, WPI's new course in bioprocess technology is funded through a partnership with local industries and with the quasi-public Bay State Skills Corp. Students receive hands-on experience running large-scale bioprocess equipment at the Norton Co. in Worcester. Millipore Corp. has donated bioprocess equipment, and a much broader industry-education collaborative process will undoubtedly result.

At Tufts University's two-year-old interdisciplinary Biotechnology Engineering Center, 20 Massachusetts biotech companies are helping to underwrite new courses in protein purification (separation science) and applied enzymology.

At the Tufts Center, evening post-graduate courses are offered for professional researchers already affiliated with biotech firms who wish to upgrade their expertise and for engineers and scientists wishing to acquire new skills for work with biotech firms. This model may be of use to other New England states once the NEBHE survey has been completed and the labor shortages for biotech firms have been identified.

In another important project, the University of Connecticut has recently announced the formation of an interdisciplinary Biotechnology

*As a first step, the board of higher education in each New England state should take inventory of the biomedical campus offerings within its state.

Center. Expensive scale-up and purification equipment has been purchased with a $250,000 grant from the Connecticut Board of Higher Education. This new capability will broaden the research capacity of the university's chemical engineering and biology departments and better equip master's degree graduates to assist Connecticut and other biotech firms.

The region is also fortunate to have an NSF-funded, cross-disciplinary Biotechnology Process Engineering Center at MIT. With $20 million from NSF over five years, the center is conducting generic applied research involving biotechnology scale-up and manufacturing, training students at all levels, and making available short-term courses and lab practicums for scientists from industry.

With respect to other levels of skill training, Boston University Medical School has leased space in Roxbury's Crosstown Industrial Park for a new medical technology training program for high school graduates. The program will offer training in skills necessary for entry into biotech industries and medical laboratories.

Where advanced training could be enriched by study in countries possessing strength in scale-up processes, such as West Germany and Japan, the commission encourages New England universities to facilitate their graduate students' work abroad. While an extraordinary number of foreign graduate students obtain engineering and science degrees in the United States and return home with invaluable expertise and American contacts in academia and industry, the reverse does not happen. Here is clearly a case where the reverse could occur to the nation's—and the region's—advantage. Finally, New England states without established bioprocess programs might reserve student spaces and provide underwriting (through contracts) so that some of their residents could enroll in bioprocess courses and programs already available in the region. If their residents return to their home state and use their skills for a certain length of time, then the home state's tuition assistance could be forgiven. A similar arrangement has worked for decades with the health-profession student contract program operated by NEBHE.

In this connection, NEBHE might consider adding a bioprocess engineering component to its regional student contract program. This would enable a state without such specialized programs to secure guaranteed access to those already in operation in a neighboring New England state, and thereby ensure that a sufficient number of its residents acquired the needed expertise.

■ **ISSUE: Many municipalities in New England do not have regulations governing biotechnology research and manufacturing.**

In the summer of 1987, the National Academy of Sciences issued a position paper on the regulation of biotechnology products, pointing out that rigid and strict controls on most such products are unjustified. The academy concluded: "There is no evidence that unique hazards exist either in the use of recombinant DNA techniques or in the transfer of genes between unrelated organisms."

A similar view has been expressed by Frank Young, commissioner of the U.S. Food and Drug Administration: "There have been *no* significant safety problems during the more than 10 years that new biotechnological techniques have been used in laboratories or applied by industry."

Three years ago, the outcry was that FDA delays of up to 36 months were adversely affecting the competitiveness of newly formed biotech corporations. The FDA, for its part, has accelerated the approval process by which it evaluates new drugs for their safety and efficacy, and the commission members express support for these efforts to encourage commercialization within the context of public safety and health. But more needs to be done.

In another move that strengthened American and New England biotech competitiveness, U.S. Sen. Edward Kennedy of Massachusetts led the way in 1986 for repeal of a federal law barring U.S. drug companies from selling abroad any product not yet approved by the FDA, even if the drug had been approved by the country wishing to import it. Because of this drug export prohibition, two Boston biotech corporations had set up production facilities in Europe and others were considering such a move. This commission supported congressional passage of the Kennedy bill, which became law—The Pharmaceutical Export Amendments of 1986—in early 1987.

Unquestionably, these are important changes in federal regulation. Regrettably, municipal governments have been slow in developing consistent rules and guidelines governing biotech activity. The commission strongly believes that now is the time for New England municipalities to address the issue so that biotechnology research and manufacturing can take place in a well-understood and predictable regulatory climate. At the minimum, local regulations should not hinder biotech development.

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■ **RECOMMENDATION: New England municipalities should adopt the model guideline regulations governing biotechnological research and manufacturing promulgated by NIH.**

West Greenwich, R.I. had adopted the NIH guidelines covering recombinant DNA research before business officials from WelGen Manufacturing, Inc. began exploring a possible production site in the city. The signal was thus clear that local government understood the importance of having realistic and appropriate biotechnology regulations already in place.

The commission recommends that other municipalities adopt the NIH code. In order to facilitate this process, New England's municipal leagues should assume the initiative, working with the U.S. Conference of Mayors and the National League of Cities.

■ **ISSUE: The New England states offer very few production and manufacturing incentives to small biotechnology companies.**

The commission is concerned that New England will not be one of the primary sites for the production and manufacturing of biomedical and biotechnological products. This has been a recurring theme of this report.

First, large pharmaceutical houses headquartered outside New England (there are none headquartered within New England) are increasingly providing the hefty financing needed for later rounds of R&D. The challenge, as several biotech business leaders have explained, is to avoid "selling the soul of your company." It may be inevitable that many small companies, as they struggle financially to move into production and manufacturing, will eventually be absorbed by the larger houses. If this happens, manufacturing will probably take place outside New England.*

Second, many European countries may step up their campaigns to assist these start-up companies and to have them establish their production facilities abroad. In the cases of Scotland and Holland, in particular, the national governments have made available generous low-cost loans to American biotech start-ups that will establish their production facilities in these countries. Without question, this is one strategic way to participate in the next technological revolution.

* One promising sign to the contrary is a manufacturing joint venture that will soon begin in Rhode Island between Genetics Institute in Boston and a British pharmaceutical firm.

Third, New England leaders may be caught in a self-fulfilling prophecy; namely, that the region's role in the future will be more on the research than on the product development side. With its stronghold of first-rate academic institutions and its critical mass of research, the region makes its unique contribution through brain power and ideas. It may seem inevitable that others will enjoy the jobs and taxes generated by the actual manufacturing of inventions flowing from the "intellectual center."

Finally, the New England states have shown commitment and imagination in setting up incubator centers for young high-tech and biotech companies. The Science Park Development Corp. in New Haven is the premier example. However, these states have not as yet demonstrated the same commitment to assist "adolescent" biotech companies in "growing" into vertically integrated companies.

■ **RECOMMENDATION: The New England Governors' Conference should create a task force to consider state incentives for the production and manufacturing of biomedical products.**

The commission recommends that the New England Governors' Conference create a task force of leaders from the financial, government and biomedical communities to consider appropriate incentives to ensure that the region captures the subsequent production development of these industries. Inasmuch as the New England Governors' Conference has extensively addressed such regional concerns as energy, capital formation and health, it is the logical regional entity to addresss this issue.

To this end, the New England Governors' Conference should examine the incentives now in place in other states to encourage and capture the production element in new technology companies. For example, the states could offer low-cost loans to be used in constructing production facilities. Tax breaks (such as accelerated depreciation) on such facilities might be considered. Moreover, no New England state provides for a research credit even though several states outside of New England have such a provision. While still allowing the deduction of R&D expenditures, California now provides for an 8 percent credit on incremental R&D and a 12 percent credit for basic university research grants. Louisiana recently enacted legislation that entitles taxpayers to a credit of 35 percent against their income tax for their contributions to the state's Dedicated Research Investment Fund for funding biomedical and biotech research and education. The viability of such incentives

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should be considered by New England policymakers.

A rule in states including Massachusetts and Connecticut that limits the the carry-forward of operating losses to five years has been called unfair by some biotech business leaders. Indeed, in New England, only Maine, Rhode Island and Vermont conform to the federal 3-year carry-back and, more importantly, 15-year net operating loss carry-forward provisions.

The NOL provisions are very important tax considerations to a biopharmaceutical company. These companies face much longer time lags between the initial discovery and the marketable product—due to the extensive animal and human trials as well as the FDA approval process. This is a handicap unique to biotech companies. Thus, the commission members conclude that the characteristics of biotechnology companies provide a strong case for state provision of special help.

The New England states that do not conform to the federal carry-forward and carry-back tax provision should modify their tax codes to conform with these federal tax provisions. Massachusetts policymakers are considering adopting a 15-year carry-forward period in certain limited cases, such as for research-oriented companies. Again, this is a policy change that ought to be considered in light of the importance of biomedical/biotech activity to the region's economy in future years.

■ **RECOMMENDATION: The New England Congressional delegation should support legislation to broaden and make permanent the federal R&D tax credit and to revise the tax code to make R&D limited partnerships a viable source of research support.**

In order to encourage continued investment in R&D, Congress should restore the R&D tax credit to its original 25 percent incremental rate and make it a permanent part of the tax code. Under the leadership of the region's Washington delegation, Congress also should exempt R&D limited partnerships from the passive activities credit limitations enacted as part of the Tax Reform Act of 1986. These limitations have made R&D limited partnerships—which have been a major source of R&D funds for biotechnology firms, in particular—much less attractive because fewer individuals can utilize the tax credit.

Over the longer term, the New England congressional delegation should play a lead role in ensuring that national tax and other policies encourage the successful development of the biomedical/biotech industries. At stake is not only regional competitiveness, but U.S. competitiveness within the much broader context of dynamically changing international markets.

Appendix

Medical Schools and Their Major Affiliated Teaching Hospitals

CONNECTICUT

University of Connecticut Medical School
John Dempsey Hospital, University of Connecticut Health Center
St. Francis Hospital and Medical Center
Hartford Hospital
Mt. Sinai Hospital
Veterans Administration Medical Center, Newington
St. Mary's Hospital*
Waterbury Hospital*

Yale University Medical School
Yale-New Haven Hospital
Bridgeport Hospital
Danbury Hospital
Hospital of St. Raphael
St. Vincent's Medical Center
Veterans Administration Medical Center, West Haven

Other**
Stamford Hospital

Source: *COTH Directory, 1987*, Council of Teaching Hospitals, Association of American Medical Colleges.

Note: COTH lists only major affiliates. Thus, not all of New England's teaching hospitals are listed in this appendix.

* Also affiliated with Yale University Medical School.

** Stamford Hospital is a major teaching hospital in Connecticut; it is affiliated with New York Medical College, Valhalla, N.Y.

MAINE

Other*
Maine Medical Center, Portland

MASSACHUSETTS

Boston University Medical School
University Hospital
Carney Hospital
Veterans Administration Medical Center, Boston**
Boston City Hospital***

Harvard University Medical School
Brigham and Women's Hospital
Beth Israel Hospital
Children's Hospital Medical Center
Dana-Farber Cancer Institute***
Massachusetts Eye and Ear Infirmary
Massachusetts General Hospital
McLean Hospital
Mount Auburn Hospital
New England Deaconess Hospital

Tufts University Medical School
New England Medical Center
Baystate Medical Center
Faulkner Hospital
St. Margaret's Hospital for Women
St. Elizabeth's Hospital

University of Massachusetts Medical School
University of Massachusetts Hospital
Berkshire Medical Center
Worcester Memorial Hospital
St. Vincent Hospital

* Maine Medical Center is affiliated with the University of Vermont Medical School. Maine does not have a medical school.

** Also affiliated with Tufts University Medical School.

*** Not a member of COTH.

NEW HAMPSHIRE

Dartmouth Medical School
Mary Hitchcock Memorial Hospital

RHODE ISLAND

Brown University Medical School
Rhode Island Hospital
Pawtucket Memorial Hospital
Roger Williams General Hospital
Veterans Administration Medical Center, Providence
Women and Infants Hospital
Miriam Hospital

VERMONT

University of Vermont Medical School
Medical Center Hospital of Vermont

Other*
Veterans Administration Medical Center, White River Junction, Vt.*

* The Veterans Administration Medical Center in White River Junction, Vt., is a major teaching hospital. It is affiliated with Dartmouth Medical School, Hanover, N.H.

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